COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 25/05/2000
C(2000) 1407

COMMISSION DECISION

of 25/05/2000

granting the marketing authorization for the medicinal

product for human use,

"PegIntron - Peginterferon alfa-2b"

ONLY THE FRENCH AND THE DUTCH TEXTS ARE AUTHENTIC.

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], and in particular Article 10(1) and (2) thereof,

Having regard to the application submitted by SP Europe, on 26 March 1999, under Article 4(1) of Regulation (EEC) No 2309/93, concerning the medicinal product, "PegIntron - Peginterferon alfa-2b",

Having regard to the opinion of 17 February 2000 of the European Agency for the Evaluation of Medicinal Products, formulated by the Committee for Proprietary Medicinal Products,

Whereas:

(1) The medicinal product, "PegIntron - Peginterferon alfa-2b", complies with the requirements of Council Directives 65/65/EEC[2], 75/318/EEC[3] and 75/319/EEC[4], as last amended by Directive 93/39/EEC[5];

[1] OJ No L 214, 24. 8. 1993, p. 1.
[2] OJ No 22, 9.2.1965, p. 369/65.
[3] OJ No L 147, 9.6.1975, p. 1.
[4] OJ No L 147, 9.6.1975, p. 13.
[5] OJ No L 214, 24.8.1993, p. 22.

(2) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorization referred to in Article 3 of Regulation (EEC) No 2309/93 is hereby granted in respect of the medicinal product, "PegIntron - Peginterferon alfa-2b" whose characteristics are summarized in Annex I hereto. This medicinal product shall be entered in the Community Register of Medicinal Products under the numbers:

EU/1/00/131/001	PegIntron - 50 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 1 vial + 1 ampoule - subcutaneous use
EU/1/00/131/002	PegIntron - 50 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 1 vial + 1 ampoule + 1 injection set - subcutaneous use
EU/1/00/131/003	PegIntron - 50 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 4 vials + 4 ampoules - subcutaneous use
EU/1/00/131/004	PegIntron - 50 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 4 vials + 4 ampoules + 4 injection sets - subcutaneous use
EU/1/00/131/005	PegIntron - 50 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 6 vials + 6 ampoules - subcutaneous use
EU/1/00/131/006	PegIntron - 80 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 1 vial + 1 ampoule - subcutaneous use
EU/1/00/131/007	PegIntron - 80 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 1 vial + 1 ampoule + 1 injection set - subcutaneous use
EU/1/00/131/008	PegIntron - 80 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 4 vials + 4 ampoules - subcutaneous use
EU/1/00/131/009	PegIntron - 80 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 4 vials + 4 ampoules + 4 injection sets - subcutaneous use

EU/1/00/131/010 PegIntron - 80 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 6 vials + 6 ampoules - subcutaneous use

EU/1/00/131/011 PegIntron - 100 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 1 vial + 1 ampoule - subcutaneous use

EU/1/00/131/012 PegIntron - 100 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 1 vial + 1 ampoule + 1 injection set - subcutaneous use

EU/1/00/131/013 PegIntron - 100 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 4 vials + 4 ampoules - subcutaneous use

EU/1/00/131/014 PegIntron - 100 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 4 vials + 4 ampoules + 4 injection sets - subcutaneous use

EU/1/00/131/015 PegIntron - 100 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 6 vials + 6 ampoules - subcutaneous use

EU/1/00/131/016 PegIntron - 120 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 1 vial + 1 ampoule - subcutaneous use

EU/1/00/131/017 PegIntron - 120 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 1 vial + 1 ampoule + 1 injection set - subcutaneous use

EU/1/00/131/018 PegIntron - 120 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 4 vials + 4 ampoules - subcutaneous use

EU/1/00/131/019 PegIntron - 120 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 4 vials + 4 ampoules + 4 injection sets - subcutaneous use

EU/1/00/131/020 PegIntron - 120 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 6 vials + 6 ampoules - subcutaneous use

EU/1/00/131/021 PegIntron - 150 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 1 vial + 1 ampoule - subcutaneous use

EU/1/00/131/022 PegIntron - 150 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 1 vial + 1 ampoule + 1 injection set - subcutaneous use

EU/1/00/131/023	PegIntron - 150 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 4 vials + 4 ampoules - subcutaneous use
EU/1/00/131/024	PegIntron - 150 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 4 vials + 4 ampoules + 4 injection sets - subcutaneous use
EU/1/00/131/025	PegIntron - 150 micrograms - Powder and solvent for solution for injection - Powder: vial (glass); Solvent: ampoule (glass) - 6 vials + 6 ampoules - subcutaneous use

Article 2

The marketing authorization concerning the medicinal product referred to in Article 1 shall be subject to compliance with all the conditions, particularly those relating to manufacture and/or importation, control and issue referred to in Annex II.

Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall conform to Annex III.

Article 4

The period of validity of the authorization issued shall be five years from the date of notification of this Decision. It shall be renewable under the conditions laid down in Article 13(1) of Regulation (EEC) No 2309/93.

Article 5

This Decision is addressed to SP Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique.

Done at Brussels, 25/05/2000

For the Commission
Erkki LIIKANEN
Member of the Commision